



Docket No.: CIMA 3.0-030 CONT CONT
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Pather et al.

Application No.: 09/661,693

Group Art Unit: 1617

Filed: September 14, 2000

Examiner: U. Ramachandran

For: SUBLINGUAL BUCCAL EFFERVESCENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

It is respectfully requested that the references listed on the enclosed form be made of record and considered with respect to the above-referenced U.S. patent application. A copy of each reference which is not a U.S. patent or patent application is enclosed. Also enclosed for consideration by the Examiner is a summary of all commonly owned/assigned pending applications and granted patents in the United States and countries foreign to the United States and corresponding to the subject application (09/661,693), including United States divisional and continuing applications and further including a summary of all pending U.S. applications and granted patents based on applications directed to related technology.

Submission of the present Information Disclosure Statement should not be taken as an admission that the cited references are legally available prior art or that the same are pertinent or material.

In the event that any fee is due in connection with the present Information Disclosure Statement, the Commissioner is hereby authorized to charge the same to our Deposit Account No. 12-1095.

Dated: September 12, 2007

Respectfully submitted,

By 

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Applicant No.: 09/661,693

Docket No.: CIMA 3.0-030 CONT CONT

**SUBMISSION ACCOMPANYING AND PART OF
INFORMATION DISCLOSURE STATEMENT FOR U.S. SERIAL NO. 09/661,693**

Summary of all commonly owned/assigned pending patent applications and granted patents in the United States and countries foreign to the United States and corresponding to the subject application (09/661,693). Office actions and responses thereto by Applicant can be obtained from the relevant patent office or will be provided by Applicant upon request. Such documents are available on-line on the websites of several patent offices including, for example, the European Patent Office, which maintains a prosecution file history database (<http://www.epoline.org/portal/public/registerplus>) analogous to that of the United States Patent and Trademark Office "PAIR" database.

A patent has been granted based on the corresponding European application, EP 1082106 and having claims substantially similar to or broader* than the claims in the present application that were submitted prior to those being offered in a new amendment accompanying a Request for Continued Examination.

* Claim 1 of granted EP 1082106 reads as follows:

"A tablet for direct oral administration of a systemically distributable pharmaceutical medicament across the oral mucosa comprising: (a) fentanyl; (b) at least pH adjusting substance in an amount to permit a therapeutically sufficient concentration of the fentanyl to be present in the unionized form; and (c) an effervescent couple."

Table

Commonly Owned/Assigned Pending Applications and Granted Patents
Directed to Technology Related to the Subject Application (USSN 09/661,693)

(AS OF AUGUST 30, 2007)

List of subject application, divisional and continuing applications and granted patents.

Title: SUBLINGUAL BUCCAL EFFERVESCENT

| <u>Docket No.</u> | <u>CC</u> | <u>Serial No./ Patent No./ Pub. No.</u> | <u>Filing/Grant Date</u> | <u>Status</u> |
|------------------------------|-----------|---|------------------------------|------------------|
| CIMA 3.0-030 CONT CONT | US | 09/661,693 | 14SE2000 | Filed Pending |
| CIMA 3.0-030 CONTCONTCONT | US | 10/080,016 6,974,590 | 20FE2002 13DE2005 | Filed GRANTED |
| CIMA 3.0-030 CONT | US | 09/327,814 6,200,604 | 08JE1999 13MR2001 | Filed GRANTED |
| CIMA 3.0-030 CONCONDIVCONCON | US | 11/511,098 2006-029219 | 28AU2006 | Filed Pending |

List of all pending applications and granted patents in countries foreign to the United States and corresponding to the subject application (09/661,693).

Title: SUBLINGUAL BUCCAL EFFERVESCENT

| <u>Docket No.</u> | <u>CC</u> | <u>Serial No./ Patent No.</u> | <u>Filing/Grant Date</u> | <u>Status</u> |
|---------------------------|-----------|-----------------------------------|------------------------------|------------------|
| CIMA 3.4-030 CON DIVDIV | AU | 2007203233 | 11JL2007 | Filed Pending |
| CIMA 3.4-030 CON DIV | AU | 2004242477 | 22MR2000 | Filed Pending |
| CIMA 3.4-030 CONT DIV | CA | 2569674 | 19DE2006 | Filed Pending |
| CIMA 3.4-030 CONT | CA | 2333375 2333375 | 22MR2000 28MY2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | EP | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT EPDIVI | EP | 03029911.9 | 22MR2000 | Filed Pending |
| CIMA 3.4-030 CONT EPDIVII | EP | 03029877.2 | 22MR2000 | Filed Pending |
| CIMA 3.4-030 CONT | AT(EP) | 00919523.1 E350017 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | BE(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | CH(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | CY(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | DE(EP) | 00919523.1 60032691.8 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | DK(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | ES(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |

Title: SUBLINGUAL BUCCAL EFFERVESCENT

| <u>Docket No.</u> | <u>CC</u> | <u>Serial No./ Patent No.</u> | <u>Filing/Grant Date</u> | <u>Status</u> |
|-------------------|-----------|-----------------------------------|------------------------------|------------------|
| CIMA 3.4-030 CONT | FI(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | FR(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | GB(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | GR(EP) | 00919523.1 3060798 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | IE(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | JP | 607609/2000 | 22MR2000 | Filed Pending |
| CIMA 3.4-030 CONT | LI(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | LU(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | MC(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | NL(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | PT(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |
| CIMA 3.4-030 CONT | SE(EP) | 00919523.1 EP1082106 | 22MR2000 03JA2007 | Filed GRANTED |

Application No.: 09/661,693

Docket No.: CIMA 3.0-030 CONT CONT

List of all pending applications and granted patents in the United States and directed to technology related to the subject application (09/661,693).

Title: EFFERVESCENT DRUG DELIVERY SYSTEM FOR ORAL ADMINISTRATION

| <u>Docket No.</u> | <u>CC</u> | <u>Serial No./ Patent No.</u> | <u>Filing/Grant Date</u> | <u>Status</u> |
|----------------------------|-----------|-----------------------------------|------------------------------|------------------|
| CIMA 3.0-031 | US | 09/302,105 6,350,470 | 29AP1999 26FE2002 | Filed GRANTED |
| CIMA 3.0-031 DIVCONT I | US | 10/021,486 6,509,036 | 29OC2001 21JA2003 | Filed GRANTED |
| CIMA 3.0-031 DIVCONT II | US | 10/021,109 6,641,838 | 29OC2001 04NO2003 | Filed GRANTED |
| CIMA 3.0-031 DIV | US | 09/613,270 6,391,335 | 10JL2000 21MY2002 | Filed GRANTED |
| CIMA 3.0-031 DIVCONTIICONT | US | 10/346,829 6,764,696 | 18MR2003 20JL2004 | Filed GRANTED |

Title: SUBLINGUAL BUCCAL EFFERVESCENT

| <u>Docket No.</u> | <u>CC</u> | <u>Serial No./ Patent No./ Pub. No.</u> | <u>Filing/Grant Date</u> | <u>Status</u> |
|------------------------|-----------|---|------------------------------|------------------|
| CIMA 3.0-036 CONTICONT | US | 10/936,185 2005-0031677 | 08SE2004 | Filed Pending |

Title: PHARMACEUTICAL COMPOSITIONS FOR RECTAL AND VAGINAL ADMINISTRATION

| <u>Docket No.</u> | <u>CC</u> | <u>Serial No./ Patent No./ Pub. No.</u> | <u>Filing/Grant Date</u> | <u>Status</u> |
|------------------------|-----------|---|------------------------------|------------------|
| CIMA 3.0-038 | US | 09/664,870 6,576,250 | 19SE2000 10JE2003 | Filed GRANTED |
| CIMA 3.0-038 CONTICONT | US | 10/946,556 2005-0037072 | 21SE2004 | Filed Pending |

Application No.: 09/661,693

Docket No.: CIMA 3.0-030 CONT CONT

Title: GENERALLY LINEAR EFFERVESCENT ORAL FENTANYL DOSAGE FORM AND METHODS OF ADMINISTERING

| <u>Docket No.</u> | <u>CC</u> | <u>Serial No./ Patent No./ Pub. No.</u> | <u>Filing/Grant Date</u> | <u>Status</u> |
|-------------------|-----------|---|------------------------------|------------------|
| CIMA 3.0-052 IIA | US | 11/026,132 2005-0169989 | 30DE2004 | Filed Pending |

Title: GENERALLY LINEAR EFFERVESCENT ORAL FENTANYL DOSAGE FORM AND METHODS OF ADMINISTERING

| <u>Docket No.</u> | <u>CC</u> | <u>Serial No./ Patent No./ Pub. No.</u> | <u>Filing/Grant Date</u> | <u>Status</u> |
|-------------------|-----------|---|------------------------------|------------------|
| CIMA 3.0-052 IIB | US | 11/026,327 2005-0142197 | 30DE2004 | Filed Pending |

Title: EFFERVESCENT ORAL FENTANYL DOSAGE FORM AND METHODS OF ADMINISTERING FENTANYL

| <u>Docket No.</u> | <u>CC</u> | <u>Serial No./ Patent No./ Pub. No.</u> | <u>Filing/Grant Date</u> | <u>Status</u> |
|-------------------|-----------|---|------------------------------|------------------|
| CIMA 3.0-052 III | US | 11/027,353 2005-0142198 | 30DE2004 | Filed Pending |

Title: EFFERVESCENT ORAL OPIATE DOSAGE FORMS AND METHODS OF ADMINISTERING OPIATES

| <u>Docket No.</u> | <u>CC</u> | <u>Serial No./ Patent No./ Pub. No.</u> | <u>Filing/Grant Date</u> | <u>Status</u> |
|-------------------|-----------|---|------------------------------|------------------|
| CIMA 3.0-052 IV | US | 11/026,759 2005-0163838 | 30DE2004 | Filed Pending |

Title: GENERALLY LINEAR EFFERVESCENT ORAL FENTANYL DOSAGE FORM AND METHODS OF ADMINISTERING

| <u>Docket No.</u> | <u>CC</u> | <u>Serial No./ Patent No./ Pub. No.</u> | <u>Filing/Grant Date</u> | <u>Status</u> |
|----------------------|-----------|---|------------------------------|------------------|
| CIMA 3.0-052 IIA CIP | US | 11/521,796 2007-0036853 | 15SE2006 | Filed Pending |



Used in Lieu of PTO/SB/08A/B
(Based on PTO 04-07 version)

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

| | | | |
|-------|---|----|---|
| Sheet | 1 | of | 1 |
|-------|---|----|---|

Complete If Known

| | |
|------------------------|------------------------|
| Application Number | 09/661,693-Conf. #2096 |
| Filing Date | September 14, 2000 |
| First Named Inventor | S. Indiran Pather |
| Art Unit | 1617 |
| Examiner Name | U. Ramachandran |
| Attorney Docket Number | CIMA 3.0-030 CONT CONT |

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|-----------------------|--------------------------|--|--------------------------------|--|---|
| | | Number-Kind Code ² (if known) | | | |
| | AA* | US-5,314,904 | 05-24-1994 | Egidio et al. | |
| | AB* | US-4,443,428 | 04-17-1984 | Oshlack et al. | |
| | AC* | US-5,102,666 | 04-07-1992 | Acharya | |
| | AD* | US-5,501,861 | 03-26-1996 | Makino et al. | |
| | AA* | US-6,974,590-A1 | 12-13-2005 | Pather et al. | |
| | AB* | US-20060292219-A1 | 12-28-2006 | Pather et al. | |
| | AC* | US-6,641,838-A1 | 11-04-2003 | Pather et al. | |
| | AD* | US-6,764,696-A1 | 07-20-2004 | Pather et al. | |
| | AE* | US-20050037072-A1 | 02-17-2005 | Pather et al. | |
| | AF* | US-20050163838-A1 | 07-28-2005 | Moe | |
| | AG* | US-20050169989 | 08-04-2005 | Moe et al. | |
| | AH* | US-20050142198-A1 | 06-30-2005 | Moe et al. | |
| | AI* | US-20050142197-A1 | 06-30-2005 | Moe et al. | |
| | AJ* | US-20070036853-A1 | 02-15-2007 | Agarwal et al. | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ² |
|-----------------------|--------------------------|---|-----------------------------------|--|---|----------------|
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| | BA | TW-40484 | 12-01-1981 | | | |
| | BB | TW-36236 | 04-01-1981 | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied under 37 CFR 1.98(b)(2)(iii) because that application was filed after June 30, 2003 or is available in the IPW. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS); title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|-----------------------|--------------------------|---|----------------|
| | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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|-----------------------|--------------------|
| Examiner Signature | Date Considered |
|-----------------------|--------------------|